

AUG - 8 2003

510(k) Summary - Opus™ Spinal System – Additional Indications

Proprietary Name:	Opus™ Spinal System
Common Name:	Spinal Fixation Appliances
Regulatory Class:	Class II
Classification Name and Reference:	Spinal Interlaminar Fixation Orthosis 21 CFR 888.3050 Pedicle Screw Spinal System 21 CFR 888.3070
For Information contact:	Karen Ariemma, Regulatory Affairs Specialist Howmedica Osteonics Corp. 59 Route 17 Allendale, NJ 07401-1677 Phone: (201) 831-5718 Fax: (201) 831-6038
Date Summary Prepared:	June 19, 2003

The purpose of this premarket notification is to add indications and to market the Howmedica Osteonics predicate OSS/Diapason and Xia® Titanium Hooks with the Opus™ Spinal System.

Predicate Device Information:

The Opus™ Spinal System was determined substantially equivalent via 510(k)s K993402 and K014229. The Multi-Axial Cross-Connector (MAC) was determined substantially equivalent for use with the Opus™ Spinal System via 510(k) K003490. The Opus™ Spinal System is made up of a range of screws, which are compatible with both the rod and plate components of the system. The components of the system are manufactured from ISO 5832/3 Titanium Alloy (Ti-6Al-4V).

Intended Use:

The Opus™ Spinal System is intended for posterior, noncervical pedicle and non-pedicle fixation for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e. fracture and dislocation); spinal stenosis; curvatures (i.e. scoliosis, kyphosis and/or lordosis); tumor; pseudarthrosis; and failed previous fusion.

The Opus™ Spinal System is also intended to be used in conjunction with the titanium hooks from the OSS/Diapason Spinal System and the Xia Spinal System. The Opus™ Spinal System is also intended to be used in conjunction with the Multi-Axis Cross Connectors.

Performance Data:

Static and fatigue test results show the constructs of the Opus™ Spinal System demonstrated comparable mechanical properties to the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 8 2003

Ms. Karen Ariemma
Regulatory Affairs Specialist
Howmedica Osteonics Corporation
59 Route 17
Allendale, New Jersey 07401-1677

Re: K030369

Trade/Device Name: Opus™ Spinal System
Regulatory Number: 21 CFR 888.3070, 21 CFR 888.3050
Regulation Name: Pedicle screw spinal system, Spinal interlaminar fixation orthosis
Regulatory Class: III
Product Code: NKB, MNI, MNH, KWP
Dated: June 19, 2003
Received: June 20, 2003

Dear Ms. Ariemma:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative
and Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

510(k) Number (if known): K030369Device Name: Opus™ Spinal System

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter Use _____ (Per 21 CFR 801.109)
(Optional Format 1-2-96)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K030369